AUG. 23

INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Changes to the rules on prescribing and dispensing medicines and healthcare products

As part of the measures to improve access to medicines, Ministerial Order 263/2023 of 17 August introduced changes to the rules for prescribing and dispensing medicines and healthcare products. These changes are aimed at facilitating access for clinically stabilised patients with chronic diseases to the long-term medication they need, by avoiding the need for these patients to go to the health centre just to renew their prescriptions.

As a result, the following will now be possible:

- In each act of prescribing through paperless prescription:

  i) In the case of certain medicines intended for long-term treatment[1], the number of packs necessary to ensure treatment for 12 months may be prescribed;

  ii) In the case of certain medicines intended for short or medium-term treatment[2], prescriptions may contain a higher number of packs than permitted[3], provided that the prescription is justified by the dosage or by a prolonged absence from the country. The reasons must also be recorded in the patient's medical record and the quantities must be appropriate and adapted to the dosage and duration of treatment.

These changes are aimed at facilitating access for clinically stabilised patients with chronic diseases to the long-term medication they need, by avoiding the need for these patients to go to the health centre just to renew their prescriptions.

Eduardo Nogueira Pinto
Ricardo Rocha
Tiago Linhares Carneiro
Healthcare, Life Sciences & Pharmaceuticals team

1 The medicinal products listed in Table 2 of the Annex to Ministerial Order 1471/2004 of 21 December.
2 The medicinal products listed in Table 1 of the Annex to Ministerial Order 1471/2004 of 21 December.
3 In other words, more than two packs or more than four packs in the case of single-dose packs.

In line with the changes introduced, the period of validity of prescriptions has been modified. Prescriptions are valid for 12 months.

- The pharmacy may dispense other packs of the prescribed medicine with an equivalent pharmaceutical form and/or dosage in situations of shortage with a high impact on public health, identified by INFARMED, I.P. (the Portuguese National Authority for Medicines and Healthcare Products).

These changes to the rules on prescribing and dispensing medicines are accompanied by measures to monitor patient compliance and the safety and efficacy of treatments:

- the prescribing doctor now has access, at the time of the prescription, to the history of prescriptions and dispensations made to the patient;

- the pharmacist has access, with the patient's consent, to all prescriptions issued or dispensed in the previous 12 months;

- pharmacies are only allowed to dispense the number of packs necessary to ensure the patient's treatment for 2 months, so that patients can be monitored and advised by pharmacists at regular intervals for the duration of the prescription[4]. However, in exceptional and properly justified situations (including loss or theft of medicines, or prolonged absence from the country), pharmacies may dispense a larger number of packs;

- the pharmacist and the prescribing doctor can communicate and exchange information via the computerised system and the pharmacist can, if he or she considers it necessary, send therapeutic notes for each medicine or health product prescribed.

Finally, in line with the changes introduced, the period of validity of prescriptions has been modified. Prescriptions are valid for 12 months, except in the case of (i) manual prescriptions, (ii) paper prescriptions for certain medicines intended for short or medium-term treatment, and (iii) paperless prescription lines for certain medicines intended for short or medium-term treatment that do not fall under the possibility of exceeding the permitted number of packs, which are valid for 30 days[5]. ■

4 Whenever it is not possible to determine the quantity of packs needed to ensure treatment for two months, pharmacies may only dispense a maximum of two packs per month, or four packs per month in the case of single-dose packs.

5 The validity period starts on the day following the date of the relevant prescription.